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Section: MAIN NEWS

DRUG INDUSTRY OVERCHARGING MEDICAID PRESCRIPTIONS COST TAXPAYERS MILLIONS OF EXTRA DOLLARS

John Winn Miller Herald-Leader Frankfort bureau

FRANKFORT -- Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor, according to government and industry officials.

One federal study put the figure at $128 million a year. But reforms in Texas indicate it could be far more than that or, as one Texas Medicaid official put it, a "staggering" amount.

Using Texas as a guide, the same reforms in Kentucky could save the state about $3 million.

The problem, officials say, is that a system designed to save taxpayers' money has been thrown out of whack by pricing data often described in the pharmaceutical industry as "meaningless" or a "joke."

The system is distorted even further by drug companies that publish prices that are dramatically higher than the prices they actually charge pharmacies. The sales technique, called "playing the spread," allows some pharmacists a larger profit margin on Medicaid drugs and frequently forces companies that play by the rules to lose business.

In Florida, for example, Medicaid officials found they were paying an average of $1.08 too much for each prescription drug because the published prices were inflated. Other states cite examples of published prices' being triple what pharmacists really paid.

Pharmacists, in turn, claim they are being squeezed to death by paper work and by low payments from Medicaid and private insurance companies that also cover drug purchases for clients. And the pharmacists say that what some perceive as overpay-

ments are actually discounts they earn by being good businessmen.

Attempts to reform the system at the federal level and in many states have been stymied by intense political pressure.

"Its a dastardly system any way you go," said Kathleen McGee, vice president for trade and professional relations for Barr Laboratories Inc.

The system evolved gradually after Medicaid was established in 1965 as a joint federal-state program to bring health care to the poor and some aged, blind and disabled people. In 1985, there were 22 million people in the program.

Each state is allowed to administer its Medicaid program within broad limits set by the federal government. Federal money, which totaled $37.5 billion in 1985, pays for from 50 percent to 78 percent. In 1985, Medicaid paid $2.3 billion for outpatient prescription drugs.

Over the years, a system to pay pharmacies for prescription drugs was devised to ensure that Medicaid was getting not only a fair price but also good discounts as a bulk buyer of drugs and as a public service.

The reimbursement system tried to assure that Medicaid never paid more for outpatient drugs than private customers and that it paid much less in most cases.

To avoid large retail markups, the rule for Medicaid payments was that pharmacies would be reimbursed by the government only for the cost of the ingredients of the drugs plus a dispensing fee to cover expenses and give them some profit.

But many officials said those lower Medicaid prices weren't nearly as low as they should have been.

A crucial number

The critical factor in all the state and federal payment formulas is the price pharmacies pay for ingredients.

Since it would be impossible to ask every pharmacy what it pays, Medicaid programs try to get prices from manufacturers and from common reference books, known as the Red Book, Blue Book and Medispan. In most cases, the figures are provided to the publications by the drug companies.

But the publications don't print what average customers pay. Instead, they print what are known as Average Wholesale Prices, which theoretically represent how much it would cost an average pharmacy to buy each drug from a wholesaler or distributor. Those prices do not, however, take into account the wide variety of discounts routinely available to pharmacies.

Nonetheless, Average Wholesale Prices have become the primary building block not

only in most state and federal Medicaid payment formulas but also in many formulas used by private insurance companies as well.

And that is the heart of the controversy.

"The (Average Wholesale Price) is a joke," said Valerie Marzani, director of regulatory affairs for Rugby Laboratories, one of the largest U.S. generic drug manufacturing companies. "It has largely become a farce because many companies have abused it and continue to abuse it."

Many state Medicaid officials agreed.

The Average Wholesale Price "just doesn't mean anything. It has no connection to what pharmacists really purchase the drug for," said David Feinberg, a top Pennsylvania Medicaid official.

Others are just as quick to defend the numbers.

"They are realistic approximations of the prices pharmacists are getting across-the-board. Every kind of price that one would attempt to use for this, you have to understand, at some level is not going to be perfect," said Todd Dankmyer, vice president for communications of the National Association of Retail Druggists.

The trouble in Kentucky

But the experience in Kentucky and other states indicates that there is a problem.

In Kentucky, there are 340,000 Medicaid recipients. This fiscal year, Medicaid will spend about $600 million on them -- $35 million of it for outpatient prescription drugs.

Kentucky gets its prices from the medical reference books, plus periodic updates from some drug companies doing business in the state. It then automatically subtracts 5 percent from the Average Wholesale Prices and adds a $3.25 dispensing fee.

Early last year, Kentucky Medicaid officials developed "a general concern" that drug prices might be excessive, according to R. Hughes Walker, the state's Medicaid commissioner.

He said that after a number of drug companies complained -- and some produced documentation -- about inflated Average Wholesale Prices, he fired off a letter last summer to all companies doing business in Kentucky.

The letter said that pricing information given to Kentucky "sometimes bears little, if any, relationship to the prices at which the respective products actually are sold to pharmacies."

It went on to demand that the companies submit what pharmacists really pay for the drugs and not the published Average Wholesale Prices.

At first, there was little response, and some companies even refused to cooperate.

But then Medicaid officials began getting company catalogs, either on their own or from competitors, that listed the real drug prices that pharmacies were paying.

Walker said they discovered that at least one generic drug company had two catalogs -- one with Average Wholesale Prices, apparently to show to Medicaid officials for reimbursements, and another with its real, lower prices to show to pharmacies.

Since then, the state has lowered more than 400 prices in its list of 3,960 approved drug products.

Walker said that he had referred a number of cases to the state attorney general's office, but that there wasn't sufficient evidence of wrongdoing for any prosecutions. He said the state probably was losing millions of dollars because it couldn't get real drug prices.

Some of the price changes in Kentucky were small, but many others were substantial.

For example, state Medicaid officials said a drug called sulfinpyrazone, used to treat chronic gouty arthritis, was listed by one company, Zenith Laboratories, in the 1987 Red Book as having an Average Wholesale Price of 16.69 cents for each 250 mg. tablet (based on a bottle of 100 tablets).

But early this year, Medicaid officials in Kentucky said they discovered that it was being sold to pharmacies for only 8.88 cents a tablet -- 47 percent below the published Average Wholesale Price.

Michael Marion, Zenith Laboratories director of marketing, said prices changed so quickly in the generic drug business that it might take months for states or medical publications to catch up. In addition, he said there quite often were sales promotions that could change prices drastically.

He said his company tried to be a fair as it could in setting its Average Wholesale Prices. And in fact it recently cut the prices by an average of one- third, he said.

But regardless of where it comes from, an exaggerated price does a couple of things to turn a cost-containment system into a costly system.

Playing the spread

For one thing, it can be used as part of a sales technique called "playing the

spread," a variety of industry sources say.

For example, sulfinpyrazone, mentioned above, had a published Average Wholesale Price of 16.69 cents, and that is the price most states would pay pharmacies. But the real price was 8.88 cents. So there was a 7.81-cent spread, or difference, between the Average Wholesale Price and the actual price. Therefore a pharmacist buying that drug could make a larger profit, and Medicaid would overpay.

In addition, 28 of the 48 states with Medicaid drug-reimbursement programs have set up an additional formula to cut costs by encouraging pharmacies to dispense less-expensive versions of drugs with three or more sources.

The program is called Maximum Allowable Cost. What it does is to take all types of a particular drug and set a limit for payments, usually based on the median Average Wholesale Price. Thus if there are 10 types of penicillin with 10 prices, then the price of the fifth-costliest brand becomes the maximum allowable cost, or the most the state will pay.

But if the Average Wholesale Prices are greatly exaggerated, then the median is increased, and the state will pay an inflated amount.

Drug manufacturers and distributors are acutely aware of the problems "playing the spread" creates.

Ms. McGee of Barr Laboratories said her company had been squeezed out of some sales because other companies actually advertised that they had a better spread.

In fact, many companies routinely list Average Wholesale Prices and "your price" in their catalogs to show the spread.

As a result, customers have put pressure on Barr Laboratories to increase the Average Wholesale Price listing as much as possible, Ms. McGee said.

"It really catches the manufactures in the middle. It makes us look dishonest, when we're not," said Ms. McGee, who has worked as a private pharmacist and for an industry trade association.

Getting clobbered

Moreover, companies that publish real prices often get "clobbered" in the marketplace, said Ms. McGee and officials of other drug companies.

Ms. Marzani of Rugby Laboratories said her company got "nailed to the wall" after it responded to the Kentucky letter about inflated Average Wholesale Prices with a list of what wholesalers were really charging pharmacies.

And although Rugby is considered to have some of the highest prices among generic companies, the Kentucky list is replete with companies showing prices two and

three times what Rugby charges for the same drug.

Ms. Marzani said other companies clearly were giving inflated prices. In fact, she pointed to one company listed in the Kentucky book, Par Pharmaceuticals, that lists a price for the heart drug isosorbide dinitrate that is three times higher than Rugby's price.

The catch is that Rugby buys the drug from that company and sells it under its own label. "You find the sense in it," she said.

Robert Gunther, vice president and marketing for sales of Par Pharmaceuticals, said the problem may be that the state had not caught up with price changes. He said that his company sent out changes as quickly as it could and that if states "don't take that information and go into their computer and change it, then we certainly can't be held responsible for that."

George Jones, executive director of the Kentucky Pharmacists Association, said he had received some complaints from his members about companies' promoting the difference between Average Wholesale Prices and their prices.

"They were worried about the ethics . . . but we haven't seen any laws broken," he said, adding that use of that sales technique was "extremely limited."

Inflated prices

But the problem isn't only that some companies are exaggerating Average Wholesale Prices as a sales technique. A number of studies have demonstrated that the prices generally are inflated.

In 1985, the inspector general of the Department of Health and Human Services conducted a nationwide audit of drug prices.

It concluded that Average Wholesale Prices were, on the average, 16 percent too high. In fact, of the 3,469 drug purchases analyzed, all but 14 were made at less than the Average Wholesale Price.

What the auditors discovered was what was common knowledge in the industry: Practically all pharmacies -- big and small, and regardless of location -- got discounts on the drugs they bought and were not passing those savings on to Medicaid.

It is common practice, for example, for pharmacies to get a discount just for paying their bills on time. In addition, there are volume discounts, rebates and specials to cut prices even further below the Average Wholesale Price.

The audit said those discounts were not being passed on to Medicaid and added, "We estimate that as much as $128 million could be saved annually through changes in program policy and regulations which would restrict the use of AWP (Average Wholesale Prices) as an upper limit in drug reimbursements."

The audit plus subsequent federal attempts to restrict the use of Average Wholesale Prices set off a firestorm of protest in the drug industry. But other studies pretty much confirmed the basic finding.

Jerry Wells, the pharmacist consultant for Medicaid in Florida, said Average Wholesale Prices were like the sticker prices on new cars. "Everybody gets a discount," said Wells, who has worked as a private pharmacist and a manufacturers representative.

He said the state's audit showed that the stores' average discount from Average Wholesale Prices was about 13.6 percent. In fact, he said, many pharmacists didn't realize just how large a discount they were getting.

They discovered an average $1.08 discount from the Average Wholesale Price on each prescription, he said. In other words, Florida was paying $1.08 too much for each of more than 8 million drug claims.

Wells said the state also discovered instances of companies' raising their Average Wholesale Prices without raising their real prices, apparently just to increase the spread.

As a result, Florida came up with a new payment system and increased the dispensing fees. The overall savings was 28 cents on each prescription, or about $2.2 million.

Texas saves millions

In Texas, the savings were even greater.

Robert Harriss, an assistant commissioner in Texas' Medicaid program, said that a 1985 survey turned up hair-raising examples of exaggerated prices, including one brand of penicillin that had a Red Book price of $100, "but pharmacists were buying it all day long for $30."

As a result, Texas developed a new reimbursement system that also encouraged the use of less expensive generic drugs.

Even with greatly increased dispensing fees, he estimated the savings were around $17 million a year, or 13.8 percent of the state's Medicaid drug budget. The savings on the cost of drugs alone was about $11.5 million, or about 9 percent of the $125 million drug bill for the 1987 fiscal year, Harriss said.

The experience in Texas indicates that the overpayments could be as high as $3 million in Kentucky, or about 9 percent of the state's $35 million drug bill. But cost-containment systems in place in Kentucky could make it somewhat less.

Nationally, applying the 9 percent Texas saved on drugs alone could have cut $200 million from the Medicaid bill in 1985. But putting Texas' other reforms

into effect nationwide could mean millions more in savings.

The approach Texas and Florida, among others, are taking is to require manufacturers to tell them how much they are charging wholesalers for each drug. To that, they add a set percentage to allow everyone some profit. In addition, they take the listed Average Wholesale Price and subtract up to 10 percent. Then they will reimburse the lower of the two prices.

States like Kentucky that just subtract a set amount from the Average Wholesale Price are not really solving the problem because companies can raise their Average Wholesale Prices, said Wells of Florida. In addition, that system penalizes companies that have low markups between their direct prices and Average Wholesale Prices, he said.

Some states said they were reluctant to change their systems because they feared the new administrative costs would exceed any savings.

But Harriss said those fears were unfounded. Texas has one full-time pharmacist using a computer to update the rapid changes in thousands of drug prices.

Pharmacists upset

But for pharmacists, the issue isn't that Average Wholesale Prices are too high, but too low. And they think they have been blamed unfairly for a problem that they cannot control because they do not set the Average Wholesale Prices and they do not design the reimbursement systems.

They argue that they don't make much profit on Medicaid and, in many cases, even lose money.

Pharmacists also said that even if the Average Wholesale Prices were off somewhat, everything balanced out because states pay such low dispensing fees -- from around $2 to more than $5.

"It's a ludicrous proposition that pharmacists are gouging the public through AWP," said Dankmyer of the National Association of Retail Druggists, which claims its 30,000 independent pharmacies provide 81 percent of all Medicaid pharmaceutical services.

The argument put forth most emphatically by pharmacists is that if they pay below the Average Wholesale Prices for some drugs, it is because they are good businessmen and therefore gain "earned discounts."

Medicaid officials, in turn, argue that they must be "prudent" buyers with taxpayers' money and that everyone gets the discounts. Therefore, they said, pharmacies should pass their savings along to the state.

But attempts to do that have met bitter resistance from the National Association

of Retail Druggists and other pharmaceutical organizations.

The association led the fight to force the federal Health Care Financing Administration, which administers Medicaid and Medicare for the elderly, to retreat from proposed changes in 1985 that came up after the inspector general's audit discovered the overpayments. (Medicare does not have an outpatient drug program).

"We put a lot of pressure on the Health Care Financing Administration, and they backed off," Dankmyer said.

Tremendous pressure also was brought to bear by political action committees on officials in states that tried to make drastic changes.

Pennsylvania, for example, was preparing major changes. After a difficult battle, however, the drug companies "gathered up enough political power that they were able to head this off," said Feinberg of Pennsylvania's Medicaid office.

New federal proposals

No one could be found at the Health Care Financing Administration who was willing to discuss the controversy. However, spokeswoman Ann Hoffnar said it was likely to be resolved soon when the agency announced new rules on reimbursements.

The federal government is likely to set a limit on drug prices, then give states enough flexibility to work out their own reimbursement systems, said C. Ross Anthony, associate administrator for program development in the financing administration.

The changes, however, are opposed by pharmacy trade groups, several state Medicaid officials and others in the industry.

"The problem with most of the government programs is that the prices that they set more often become a ceiling than a floor. And they have this bad habit of being pressured down," said Ms. McGee of Barr Laboratories. "So everybody is rightly leery of fixed formulas."

---- INDEX REFERENCES ----

COMPANY: BARR PHARMACEUTICALS INC; RUGBY LABS; ZENITH LABORATORIES INC

NEWS SUBJECT: (Social Issues (1SO05); Social Welfare (1SO83); Government (1GO80); Economics & Trade (1EC26))

INDUSTRY: (Insurance Regulatory (1IN40); Commercial Property & Casualty Insurance (1CO35); Pharmaceuticals & Biotechnology (1PH13); Healthcare Services (1HE13); Healthcare Services Regulatory (1HE66); Ambulatory Healthcare Practices & Management (1AM98); Healthcare Regulatory (1HE04); Pharmacy (1PH23); Drugs (1DR89); Infection Control & Epidemiology (1IN02); Financial Services (1FI37); Antibiotics

(1AN81); Financial Services Regulatory (1FI03); Infectious Diseases (1IN99); Pharmaceuticals Cost-Benefits (1PH30); Pharmaceuticals Regulatory (1PH03); Drugstores (1DR73); Property & Casualty Insurance (1PR21); Healthcare (1HE06); Healthcare Cost-Benefits (1HE10); Corporate Insurance (1XO50); Insurance (1IN97); Ambulatory Care (1AM41); Prescription Drugs (1PR52))

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date OCT 20 1992

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Cost of Dialysis-Related Drugs (A-01-91-00526)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

The attached final management advisory report summarizes the results of our review of the Health Care Financing Administration's (HCFA) proposal to change the methodology for reimbursing separately billable drugs under Medicare's end stage renal disease (ESRD) program. On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under Medicare's ESRD program to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book and similar price listings. At the request of HCFA, we initiated a review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulation and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate.

Subsequently, HCFA published final regulations (effective January 1, 1992) basing the reimbursement for separately billable drugs on single-source and multiple-source drugs as follows:

> **Single-Source Drugs** - The lower of the estimated acquisition costs (EAC) or the AWP. The EAC is based on surveys of the actual invoice prices paid for the drug.
>
> **Multiple-Source Drugs** - The lower of the EAC or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

The review results indicate that dialysis facilities purchase separately billable drugs significantly below the AWP. Instructing the Medicare fiscal intermediaries (FI) to set the reimbursement limit at the EAC rather than the AWP for selected drugs appears to be a reasonable course of action for HCFA to take in controlling Medicare program expenditures. Some facilities, however, still need to be encouraged to seek the lowest possible price for the purchase of drugs. With regard to the second objective, we were unable to identify any high volume separately billable drug that

was administered enough to include in the composite rate. However, as an alternative, HCFA should consider including the cost of all separately billable drugs into the composite rate to save on administrative costs and reduce payment errors.

We are recommending that HCFA: (1) provide the necessary guidance to the Medicare FIs to ensure a timely implementation of the EAC provision of the new Medicare drug regulations, (2) encourage providers to purchase their drugs from the most economical source, and (3) consider a methodology for folding the costs of all separately billable drugs into the composite rate.

In response to our draft report, HCFA indicated agreement with recommendations one and two and stated that it is in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of the AWP or the EAC.

Regarding the third recommendation, HCFA has deferred comment and requested information on the correlation of drug use patterns at hospital-based facilities. In addition, HCFA has requested the variation in the cost of separately billable drugs to total facility costs among the facilities surveyed. Additional comments addressing this issue follow the RECOMMENDATIONS section of our report.

Please advise us, within 60 days, on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff call George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 966-7104. Copies of this report are being sent to other interested top Departmental officials.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COST OF DIALYSIS-RELATED DRUGS

OCTOBER 1992 A-01-91-00526

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date OCT 20 1992

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Cost of Dialysis-Related Drugs (A-01-91-00526)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

This final management advisory report summarizes the results of our review of costs for dialysis-related drugs. On June 5, 1991, the Health Care Financing Administration (HCFA) published a proposal to change the methodology for reimbursing drugs under the Medicare end stage renal disease (ESRD) program to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book (Red Book) and similar price listings. At the request of HCFA, we initiated a review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulations and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate.

On November 25, 1991, HCFA published final regulations (effective January 1, 1992) basing the reimbursement for separately billable drugs on single-source and multiple-source drugs as follows:

Single-Source Drugs - The lower of the estimated acquisition costs (EAC) or the AWP. The EAC is based on surveys of the actual invoice prices paid for the drug.

Multiple-Source Drugs - The lower of the EAC or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

Prior to the new regulations, ESRD facilities were reimbursed at the lower of the facility's customary charge, the facility's actual charge, or the AWP.

Our review of 30 randomly selected dialysis facilities disclosed that most of the separately billable drugs administered during May 1991 were purchased at prices below the AWP. The median cost for two of the more frequently administered brand name drugs ranged from 15 percent to 20 percent less than AWP. Instructing the Medicare fiscal intermediaries (FI) to set the reimbursement limit at the EAC rather than the AWP for selected drugs appears to be a reasonable approach to controlling Medicare program expenditures.

Based on our analysis, the majority of facilities included in our review will recover their costs under the EAC provision. Our review also showed that the acquisition cost (invoice price) for drugs did vary by facility and, as such, drug costs for some facilities under the new regulations could be higher than the EAC. However, reimbursement under the Medicare program is based on the premise that the provider of services will not pay more than the going price and will seek to economize by minimizing its costs. Accordingly, facilities with costs that are above the EAC must be encouraged to become more prudent buyers of drugs and seek the lowest possible price.

We are also concerned about the implementation of the EAC provisions by the FIs. A review conducted by the Office of Inspector General (OIG) of separately billable drugs (CIN: A-01-90-00502) disclosed a material weakness in the system of internal controls at the FIs for the payment of separately billable drugs that resulted in over $15 million in program overpayments. Accordingly, controls are needed to ensure that these same weaknesses do not occur when the FIs implement the new EAC provisions.

In regards to the second review objective, we identified as many as 35 separately billable drugs that were administered to ESRD patients during the month of May 1991 at a random sample of 30 facilities. However, we only found three drugs (Calcijex, Imferon, and Vancocin/Vancomycin) that were administered by more than 50 percent of the sampled facilities. Even for those three drugs, the utilization varied significantly from one facility to another during the month of May 1991. It was evident from our analysis and discussions with ESRD facility administrators that the drug treatment patterns were not consistent among ESRD patients and that the types of separately billable drugs administered to patients change as new drugs become available. Consequently, facilities do not consistently administer the same type of drugs to its patients. Therefore, we were not able to develop an equitable method for modifying the composite rate for any one particular separately billable drug.

As an alternative, HCFA could consider a methodology for folding the costs of all separately billable drugs into the composite rate since these drug costs only represent 3.2 percent of total facility costs. If this method is adopted, HCFA should

utilize the most recent audited facility cost data. Having a comprehensive rate which includes all the costs relating to a dialysis treatment would save administrative costs and reduce the payment errors that have occurred in processing claims for separately billable drugs at the FIs.

We are recommending that HCFA: (1) provide the necessary guidance to the FIs to ensure a timely implementation of the EAC provision of the new Medicare drug regulations, (2) encourage providers to purchase drugs from the most economical source, and (3) consider a methodology for folding the costs of all separately billable drugs into the composite rate.

In response to our draft report, HCFA indicated agreement with recommendations one and two and stated that it is in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of the AWP or the EAC.

Regarding the third recommendation, HCFA has deferred comment and requested information on the correlation of drug use patterns at hospital-based and free-standing facilities. In addition, HCFA has requested the variation in the cost of separately billable drugs to the total facility costs among the facilities surveyed. Additional comments addressing this issue follow the RECOMMENDATIONS section of this report.

BACKGROUND

Health Insurance for the Aged and Disabled (Medicare), title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by HCFA. Medicare includes coverage for eligible persons suffering kidney (renal) failure under its ESRD program. The HCFA utilizes a prospective method of payment for dialysis services. Under this system, HCFA establishes a composite rate, per treatment, to reimburse independent renal dialysis facilities and hospital-based facilities. The Medicare program pays 80 percent of the composite rate, and payment of the remaining 20 percent (coinsurance) is the responsibility of the ESRD beneficiary. The composite rate is a comprehensive payment for all services related to dialysis treatment except for physicians' patient care services, blood, and certain drug and laboratory services that are separately billable.

Reimbursement to independent dialysis facilities for separately billable services is based on prescribed limits set forth in 42 CFR parts 405 and 415. Effective January 1, 1992, reimbursement for single-source separately billable drugs is based on the lower of the EAC or the national AWP of the drug. For multiple-source drugs, payment is based on the lower of the EAC or the median price for all sources of the

generic form of the drug. The EAC is determined based on surveys of the actual invoice price paid for the drug. In calculating the EAC of the drug, the carrier may consider factors such as inventory, waste, and spoilage. In addition to the payment for the drug, a payment is made for the cost of the supplies used to administer the drug (e.g., syringe). However, no separate payment is to be made for the staff time used to administer drugs. These services are reimbursed through the ESRD composite rate.

Based on 1990 cost report information submitted by 23 of the 30 sampled facilities, we determined that separately billable drug costs accounted for 3.2 percent of the total facility costs. For the remaining seven facilities, we were unable to determine their separately billable drug costs.

Hospital-based dialysis facilities are reimbursed for separately billable services through the hospital cost report settlement process. Medicare FIs are responsible for processing claims for separately billable drug and blood services submitted by dialysis facilities.

METHODOLOGY

On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under the Medicare ESRD program to 85 percent of the national AWP of the drug as published in the Red Book and similar price listings. At the request of HCFA, we initiated a review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulations and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate.

On November 25, 1991, HCFA published final regulations (effective January 1, 1992) basing the reimbursement for separately billable drugs on single-source and multiple-source drugs as follows:

> **Single-Source Drugs** - The lower of the EAC or the AWP. The EAC is based on surveys of the actual invoice prices paid for the drug.
>
> **Multiple-Source Drugs** - The lower of the EAC or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

To accomplish our objectives, we randomly selected 30 independent dialysis facilities using a stratified sampling plan that included 10 small, 10 medium, and 10 large facilities (*see Appendix I*). We judgmentally selected the month of May 1991, as the time frame for our analysis. Nothing came to our attention that would indicate that the treatment pattern of the patient population differed from month to month.

For each facility, we determined which separately billable drugs were administered, how often the drug was given, and the invoice price of the drugs paid during May 1991. Frequently administered drugs identified were evaluated individually for each facility to determine if the facility would recover its cost under the revised system of reimbursement.

Information regarding separately billable drugs and the frequency of administration was obtained from medical records, billing records, computer extracts of the medical records, and discussions with ESRD facility administrators and nurses. We conducted on-site reviews at 21 of the sampled facilities. For the remaining nine facilities, we sent out a facility questionnaire to obtain the requested information.

Hospital-based dialysis facilities were not included in the review because they are reimbursed through the hospital cost report settlement process as previously noted. Our review also did not address the issue of inventory cost, waste, or spoilage because of the lack of criteria available to quantify such costs.

We also obtained cost and dosage information regarding the drug Epogen which is billed outside the composite rate at a reimbursement rate of $11.00 per 1,000 units administered. The results of this analysis were not included in this review but will be addressed in a separate report.

Our review was conducted from July 1991 to December 1991 at selected dialysis facilities, the HCFA central office in Baltimore, Maryland and the Boston regional office of the OIG. On April 30, 1992 we provided HCFA with a copy of our draft report. The HCFA's written comments are appended to this report (*see Appendix IV*) and are summarized starting on page 9.

RESULTS OF REVIEW

Impact of the EAC Provisions on Separately Billable Drugs

Almost all of the separately billable drugs were purchased from drug wholesalers. Our analysis of drug invoice prices indicated that 28 of the 30 sampled facilities purchased separately billable drugs at prices less than the AWP. The median cost for two of the more frequently administered brand name drugs ranged from 15 percent to 20 percent less than the AWP. We did identify a few instances where facilities, on occasion, purchased drugs from the local pharmacy at higher prices. For instance, one facility purchased 1 gram of Vancomycin at $41.18, which was $10.04 higher than the AWP of $31.14. Our review also showed that the acquisition cost (invoice price) for drugs did vary by facility. However, as shown in Appendix II, the lowest price was not always associated with the larger facilities. The two lowest prices for Calcijex ($6.19 and $5.90) were obtained by a small and medium sized facility.

Under the new drug regulations, separately billable drugs will be reimbursed based on the lower of EAC or AWP. The EAC is determined based on surveys of the actual invoice prices paid for the drug by facilities. To comply with the new regulations, we developed an EAC for the more frequently administered separately billable drugs using the median invoice price obtained from the 30 dialysis facilities. The following chart illustrates the impact of the new regulations on the reimbursement rate to the sampled facilities:

Drugs/Dosage	EAC	AWP	Payment Difference	Number of Facilities At or Below EAC[1]	Number of Facilities Above EAC
Calcijex 1 MCGM	$ 7.34	$ 9.18	$ 1.84	19	7
Imferon 2 ML	$10.19	$11.99	$ 1.80	9	9
Vancocin/ Vancomycin 500 ML[2]	$ 5.00	$19.17	$14.17	12	9

NOTES

1 *Not all facilities administered or purchased the drug in the same dosage. To ensure adequate comparison, we limited our analysis to only 1 month, May 1991, and the same dosage.*

2 *This drug is a multiple-source drug. We used the median AWP for the generic drug.*

As shown above, Medicare program expenditures for separately billable drugs should be reduced if the EAC is properly implemented.

Even though the reimbursement rate will be reduced, our analysis disclosed that the majority of facilities included in our review will recover its costs under the EAC provision. On the other hand, the new regulations would adversely affect some facilities whose costs were above the EAC. However, the implementation of the EAC should encourage those providers to follow the prudent buyer concept in order to obtain lower prices. In any event, the EAC provision should not significantly affect

the financial status of individual facilities because separately billable drug costs account for only 3.2 percent of the total facility costs.[1]

Prior to the new drug regulations, Medicare FIs were required to reimburse independent dialysis facilities the lower of the facility's customary charge, the facility's actual charge, or the AWP. An OIG review (CIN: A-01-90-00502) identified a material weakness in the system of internal controls that resulted in significant overpayments ($15 million) made by FIs for separately billable drugs. Accordingly, we are concerned that controls are established to ensure that the EAC is properly implemented by the FIs to prevent overpayments from occurring.

Frequency of Use of Separately Billable Drugs

The HCFA requested that we obtain frequency of use data on separately billable drugs to assist in identifying high volume drugs for inclusion in the composite rate. At the time of our review, HCFA had not yet implemented a uniform coding system to identify separately billable drugs as recommended in our nationwide review (CIN: A-01-90-00502), issued July 29, 1991. Accordingly, we used patient medical and billing records to accumulate the data. Most of the facilities reviewed used 10 or less separately billable drugs during the month of May 1991. A few facilities used more, but the frequency of use of most drugs was very limited. Appendix III contains the names of 35 separately billable drugs used by at least 1 facility.

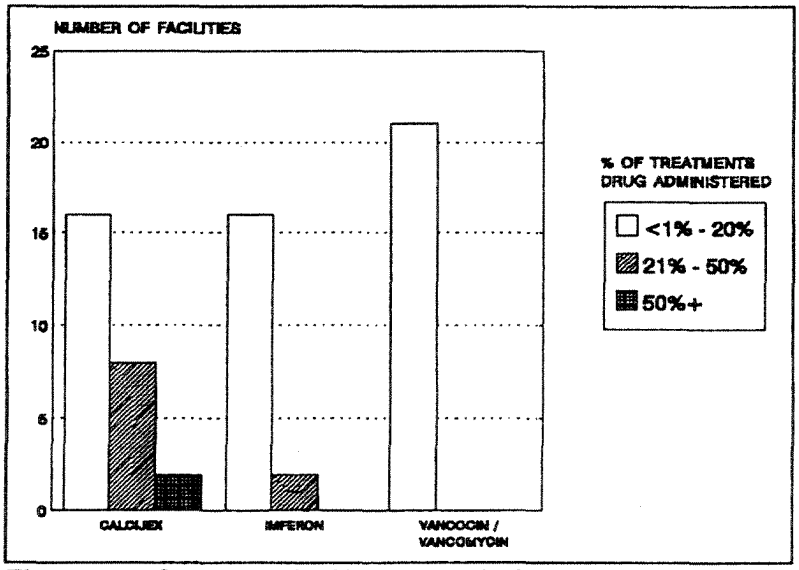

Figure 1 - Source: Facility Records for May 1991

We identified three separately billable drugs that were used by more than half of the facilities. Calcijex is used to combat bone disease in renal patients. Imferon is an iron supplement. Vancocin/Vancomycin is an antibiotic. Calcijex was used at 26 facilities,

[1] Based on 1990 cost report information submitted by 23 of the 30 sampled facilities. For the remaining seven facilities, we were unable to determine their separately billable drug costs.

Vancocin/Vancomycin at 21, and Imferon at 18. However, as Figure 1 indicates, usage patterns vary greatly among facilities. For instance, our analysis of drug usage patterns in May 1991 showed that Calcijex ranged from a low of less than 1 percent of treatments to a high of 60 percent. Imferon usage, as a percent of treatments, ranged from less than 1 percent to 32 percent and Vancocin/Vancomycin from less than 1 percent to 15 percent.

In addition, our analysis and discussion with ESRD facility administrators indicated that the type of separately billable drugs administered changes as new drugs become available. The introduction of Epogen, a red blood cell producing drug, has caused a marked decrease in the use of steroid-type drugs such as Deca-Durabolin and Nandrolone Decanoate used to increase red blood cell production in dialysis patients. Conversely, the widespread use of Epogen, which requires a sufficient level of iron stores, has increased the use of Imferon which builds up the patient's iron level. Imferon was used by 18 facilities and would have been used by more and at higher frequencies except that it is not widely available.

Considering the differences in utilization and the introduction of new types of drugs, we were not able to develop an equitable method for modifying the composite rate for any one particular type of separately billable drug. Moreover, developing a reasonable payment amount to be added to the composite rate, that would be fair to all facilities, would be a difficult task in light of all the variables previously identified. As an alternative, HCFA should consider a methodology for folding the costs of all separately billable drugs into the composite rate since these drug costs only represent 3.2 percent of total facility costs. In doing so, HCFA should utilize the most recent audited facility cost data. Having a comprehensive rate, which includes all the costs relating to a dialysis treatment, would also save administrative costs and reduce the payment errors that have occurred in processing claims for separately billable drugs at the FIs.

RECOMMENDATIONS

We are recommending that HCFA: (1) provide the necessary guidance to the FIs to ensure a timely implementation of the EAC provisions of the new Medicare drug regulations, (2) encourage providers to purchase drugs from the most economical source as required by the prudent buyer concept, and (3) consider a methodology for folding the costs of all separately billable drugs into the composite rate.

HCFA Comments

The HCFA, in its response, indicated agreement with recommendations one and two and stated that:

- it is in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of the AWP or the EAC;
- apart from implementing the new payment methodology, no additional action is needed on the part of HCFA.

Regarding recommendation three, HCFA has deferred comment and requested the following information on folding the costs of all separately billable drugs into the composite rate:

- the correlation between hospital-based and free-standing facilities with regard to the use of drugs;
- the variation among the facilities surveyed of the cost of separately billable drugs to the total facility costs.

OIG Response

Regarding hospital-based facilities, we were unable to determine similar cost data because the hospital cost report does not isolate separately billable drug costs. Nevertheless, if HCFA believes that the concept of including all drugs in the composite rate is a worthwhile objective, hospitals should be required to provide the necessary data to use as a basis for revising the composite rate.

For the 23 facilities reporting separately billable drug costs, the percent of those costs to total facility costs ranged from .0007 percent to 10.36 percent. This information was obtained from the 1990 cost reports filed with the FIs. As previously noted, for the remaining seven facilities, we were unable to determine their separately billable drug costs.

APPENDICES

APPENDIX I

INDEPENDENT DIALYSIS FACILITIES SELECTED FOR REVIEW

SMALL

	Name of Facility	City	State
1	Bakersfield Dialysis Center	Bakersfield	CA
2	BMA of Burlington	Burlington	NC
3	BMA of Guayama	Guayama	PR
4	Community Dialysis - Columbia	Columbia	SC
5	Community Dialysis Service - Winter Haven	Winter Haven	FL
6	Dialysis Center of Shreveport	Shreveport	LA
7	Dickson Dialysis Clinic Inc	Dickson	TN
8	Indian River Artificial Kidney Center	Stuart	FL
9	Kansas Nephrology Associates	Hays	KS
10	South Eastern Dialysis Center	Whiteville	NC

MEDIUM

	Name of Facility	City	State
11	Artifical Kidney Center of Suffolk	Suffolk	VA
12	BMA-Dekalb Gwinnett (BioMedical Assoc.)	Decatur	GA
13	BMA of N Philadelphia	Philadephia	PA
14	Carolina Clinic Kidney Center (REN Wilson)	Wilson	NC
15	Dialysis Center - Denver	Denver	CO
16	Inglewood Dialysis Services, Inc	Inglewood	CA
17	Melbourne Kidney Center	Melbourne	FL
18	Opelika Nephrology Referral Center Inc	Opelika	AL
19	San Diego Dialysis Center	San Diego	CA
20	S. Florida Artificial Kidney Center Inc	Miami	FL

LARGE

	Name of Facility	City	State
21	BMA of Springfield	Springfield	MA
22	BMA of Detroit	Detroit	MI
23	Central Florida Kidney Center	Orlando	FL
24	Dallas Kidney Disease Center	Dallas	TX
25	Greenfield Health Systems Corp	Dearborn	MI
26	Mervin W. Perdue Kidney Center	Alexandria	LA
27	Nephro Care Inc	Brooklyn	NY
28	Northern Louisiana Dialysis Center	Monroe	LA
29	Oak Park Community Dialysis Center	Oak Park	IL
30	University of Louisville Kidney Program	Louisville	KY

APPENDIX II

INVOICE PRICE FOR SELECTED DRUGS AT THE DIALYSIS FACILITIES REVIEWED

SEPARATELY BILLABLE DRUG	FACILITY SIZE	PER UNIT COST										NUMBER OF FACILITIES USING DRUG	EAC	AWP
CALCIJEX 1MCGM/ML (S)	SMALL	$7.93	7.52	7.34	7.34	7.34	7.19	7.19	6.19	-	-	8		
	MEDIUM	$7.52	7.34	7.34	7.19	7.19	7.19	7.16	7.02	5.90	-	9		
	LARGE	$7.93	7.71	7.52	7.45	7.34	7.34	7.34	7.27	7.19	-	9		
												26	$ 7.34	$ 9.18
IMFERON 2ML (S)	SMALL	$11.99	11.99	11.40	10.80	9.70	9.45	-	-	-	-	6		
	MEDIUM	$12.98	11.40	10.39	9.99	9.91	8.88	8.11	-	-	-	7		
	LARGE	$12.86	10.80	9.03	8.88	7.51	-	-	-	-	-	5		
												18	$10.19	$11.99
VANCOMYCIN VANCOCIN 500MG (M)	SMALL	$8.33	7.80	4.79	4.59	4.59	3.45	-	-	-	-	6		
	MEDIUM	$12.50	7.80	7.55	5.00	5.00	4.79	4.79	4.75	-	-	8		
	LARGE	$26.61	8.67	7.80	6.82	5.00	4.44	3.89	-	-	-	7		
												21	$ 5.00	$19.17

Notes:
S = Single source drug
M = Multiple source drug
- = Facility did not purchase this drug during sample month.
EAC = Estimated Aquisition Cost was calculated using the median invoice price.
AWP = Average Wholesale Price is the median Red Book price for the generic form of the drug.

APPENDIX III

LIST OF SEPARATELY BILLABLE DRUGS

Albumin
Ancef
Benadryl (I.V.)
Calcijex
Compazine
Darvon
Decadurobolin
Demerol
Depotestoserone
Desferal
Dijoxcin
Dilantin
Energix-B
Folic acid
Fortaz
Gentamicin
Hydro-cortisone
Imferon
Lanoxin
Mannitol
NaHCO3
Narcan
Premarin
Phenergan
Prolixin Decanoate
Promethazine
Recombivax
Rocephin
Talwin
Tobramycin
Urokinase
Valium (I.V.)
Vancomycin
Verapamil
Vitamin-B12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

Date JUL 28 1992

From William Toby, Jr.
Acting Administrator

Subject Office of Inspector General (OIG) Draft Management Advisory Report: Cost of Dialysis-Related Drugs (A-01-91-00526)

To Inspector General
Office of the Secretary

We have reviewed the above-referenced draft management advisory report which summarizes the results of OIG's review of the Health Care Financing Administration's (HCFA) proposal to change the methodology for reimbursing separately billable drugs under Medicare's end stage renal disease (ESRD) program.

On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under the Medicare ESRD program to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book and similar price listings. On November 25, 1991, HCFA published final regulations (effective January 1) basing the reimbursement for separately billable drugs on the payment methodology for single-source and multiple-source drugs. Prior to the new regulations, ESRD facilities were reimbursed at the lower of the facility's customary charge, the actual charge, or the AWP. At the request of HCFA, OIG initiated the review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulations, and (2) obtain the necessary data to include payment for certain high volume, separately billable, dialysis-related drugs under the prospective composite rate.

OIG found that dialysis facilities purchased separately billable drugs significantly below the national AWP. OIG recommends that HCFA:

- Provide intermediaries with the instructions needed to implement the new drug reimbursement policy promulgated in the Physician Payment Reform regulation;
- Encourage facilities to purchase drugs from the most economical source: and
- Place reimbursement for separately billable drugs in the composite rate.

We agree with the first two recommendations and defer comment on the third recommendation pending additional information from OIG. Our detailed comments are attached.

Thank you for the opportunity to review and comment on this draft management advisory report. Please advise us whether you agree with our position on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration
on Office of Inspector General (OIG) Draft Management Advisory Report:
Cost of Dialysis-Related Drugs
(A-01-91-00526)

OIG Recommendation

HCFA should provide the necessary guidance to the fiscal intermediaries to ensure a timely implementation of the estimated acquisition cost (EAC) provisions of the new Medicare drug regulations.

HCFA Response

We agree. We are in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of average wholesale price (AWP) or EAC. We plan to refer the intermediary processing the claim for ESRD separately billable drugs to the appropriate carrier for the calculation of the EAC and the AWP. Carriers are better able to make these calculations than are intermediaries, in the same sense that intermediaries look to carriers for the calculation of laboratory fee schedule amounts.

OIG Recommendation

HCFA should encourage providers to purchase drugs from the most economical source as required by the prudent buyer concept.

HCFA Response

We agree. As OIG notes, financial pressures created by the implementation of the new EAC methodology for pricing separately billable drugs should encourage providers to purchase their drugs from the most economical source. Apart from implementing the new payment methodology, no additional action is needed on the part of HCFA.

OIG Recommendation

HCFA should consider a methodology for folding the costs of all separately billable drugs into the composite rate.

HCFA Response

We defer comment on this recommendation until OIG responds to the following questions. OIG indicates that only freestanding ESRD facilities were surveyed. On what basis does OIG assume that the experience of hospital-based facilities in regard to the use of drugs is the same as that of freestanding facilities? OIG also indicates that the cost of separately billable drugs represents 3.2 percent of total facility costs for the facilities in the study. What was the variation in this percentage among the facilities?

EXHIBIT BT

OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES

CIN: _____

DRUG: Vancomycin / Vancocin

DOSAGE SIZE: 500 mg

MFG:	AWP:
LILLY	$ 7.80
ELKINS-SINN	• $ 18.81
LEDERLE STD	• $ 19.53
ABBOTT HOSP.	$ 24.88

• 18.81
• 19.53
38.34

19.17
2 ⟌ 38.34

MEDIAN COST - $19.17

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REVIEWED BY DATE

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EXHIBIT BU

Modern Healthcare

Hospitals play into hands of vendors who try to break group contracts

By Esther Kuntz

Hospitals are playing into intravenous solution manufacturers' hands as the suppliers try to break up committed volume group contracts.

Committed volume contracts are becoming a major threat to vendors as more groups sign these agreements. But some hospitals are jeopardizing their potential long-run advantage in contract negotiations by joining groups to get prices down and then using these prices to get better offers from their current vendors. This is exactly what suppliers want, because once a group contract is broken, they can jack prices up again.

Baxter Travenol Laboratories Inc., Deerfield, IL, is "doing everything possible to destroy" Joint Purchasing Corp.'s committed volume contract with Abbott Laboratories, North Chicago, IL, said Barry Novich, vice president of the New York City group.

After the group awarded Abbott the contract, Baxter reminded one of the hospitals that their contract has two years to run, a hospital official said. "Don't you think it would be appropriate for us to have a chance to meet the competition?" the Baxter representative asked.

Baxter has approached other group members in the same way, Mr. Novich said. As far as he knows, none of the other suppliers have done so. McGaw Laboratories, Irvine, CA, a division of American Hospital Supply Corp., made counter offers to two hospitals, he said, but only after the hospitals requested them.

Baxter denies initiating negotiations with JPC members after Abbott got the contract. A spokesman said the hospitals invited counter offers and that it doesn't regard such hospitals as committed to a group contract.

When asked why Baxter didn't make its best offer to the group, a company official replied, "When you take bids [as the group did] you get what you're offered, and when you negotiate [as individual hospitals are] you get what you want." He also claimed that JPC didn't award the contract to the lowest bidder.

Abbott was by far the lowest bidder on most items (see chart), Mr. Novich declared. Baxter came in with lower prices on only a few items, including some basic administration sets.

Baxter has one JPC hospital backed into a corner. Shortly after the group awarded the $6-million-a-year contract to Abbott, Baxter representatives visited the hospital to review its credit standing with the company, Mr. Novich said. The hospital fears that Baxter, a major creditor, will sue the institution for outstanding debt and put it out of business if it switches to Abbott.

There is "no substance to that concern," Baxter says. But the hospital just told JPC unofficially that it is dropping out of the contract.

Baxter is making it even easier for the hospital to continue doing business with it by offering to meet Abbott's bid, which would save the hospital $125,000 per year, according to Mr. Novich.

If committed volume I.V. contracts take hold, vendors will win or lose big

Despite such tactics, Baxter won't succeed in breaking the group agreement as it did when the Southeast Louisiana Hospital Service Corp., New Orleans, tried to negotiate an I.V. contract a year ago (MH June 1979, p. 12-13; Dec. 1979, p. 2 Mr. Novich believes.

"Those hospitals with integrity will stay with the group," he predicted. Every group member agreed to accept either Abbott or Baxter, depending on who offered the best deal. McGaw Laboratories and Cutter Laboratories, Berkeley, CA, also bid on the contract.

"If we can get two or three key institutions to sign the agreement, we will be able to convince the rest to join," Mr. Novich said. Many of the

Bids on JPC I.V. contract

High volume plastic items	Abbott	Baxter Travenol (per case of 12)
5% dextrose in water (1000 ml)	$ 9.62	$11.22
5% dextrose in water injection (500 ml)	$ 7.72	$ 9.00
5% dextrose in water normal saline (1000 ml)	$10.43	$12.12
5% dextrose in water half normal saline (1000 ml)	$10.43	$12.12
Normal saline (1000 ml)	$ 8.81	$10.32

MODERN HEALTHCARE chart/July

JPC's vice president Barry Novich

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Management

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By Vince DiPaolo
Managing Editor

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hospitals and 11 nursing homes that originally committed to the contract have signed it, including several hospitals currently supplied by Baxter.

The rest want assurance that more will sign, because for every 1,000 beds the contract loses, the group loses 1% on all discounts. If all 17,000 beds participate, the group will get about an 80% discount off current list prices for solutions and at least 50% off administration sets. Two hospitals outside the group have asked to sign the contract, which will make up for beds that drop out. JPC is also opening the agreement to other hospitals that want to join.

This particular contract is a real threat to I.V. manufacturers, according to W. Robert Friedman Jr., Montgomery Securities, San Francisco. Some of the most prestigious medical centers in the country are members of the group. Mount Sinai Medical Center, Montefiore Hospital and Lenox Hill Hospital evaluated products from all four suppliers and found many of them to be similar.

When major medical centers confirm that most I.V. products are generic, suppliers lose hospital loyalty to their products. They have only price to compete with. Nevertheless, hospitals have a tendency to stick with current suppliers to avoid retraining staffs to use different products, if they can get

Continued on page 16

Management

George Van quits Affiliates; Buncher hired to stem management turnover

By Vince DiPaolo
Managing Editor

INA Corp. last month named James E. Buncher president of its Hospital Affiliates International Inc., a subsidiary of the insurance holding company's INA Health Care Group. Formerly president of INA Healthplan Inc., another subsidiary of the INA Health Care Group, Mr. Buncher was brought in following a heavy turnover in Nashville-based Affiliates' senior management during the past 18 months.

Philadelphia-based INA announced that former Affiliates president George P. Van resigned to pursue other business. He will serve as a consultant to Affiliates, the nation's second largest operator of acute care general hospitals. Jack R. Anderson, INA Health Group president and Affiliates' chairman, said Mr. Van resigned partly because of disagreements between them about Affiliates' operating philosophy. Also, Mr. Anderson added "I am not an easy guy to work for." Mr. Anderson declined further comment on Mr. Van's departure. Sources say Affiliates will honor the two-and-a-half years left on Mr. Van's five-year contract.

Mr. Van declined comment except to say "I'm proud of Affiliates' record of dramatic profit and revenue increases under my direction." Sources inside Affiliates acknowledge that profits and revenues have tripled since Mr. Van became president in 1977.

Former and current Affiliates' executives believe a clash between the two executives' management styles was a major reason for Mr. Van leaving. Mr. Van tried to implement a team management approach and was often at odds with Mr. Anderson's individual style of management. The differences in the two executives' management styles and business orientation often slowed the decision making process, leading many frustrated senior executives to seek work elsewhere.

Mr. Buncher, who has worked for Affiliates and INA for six years, is highly regarded by both current and former Affiliates executives. They believe that because his management style is closer to Mr. Anderson's, executive decision making will be smoother and faster and the company's direction and operating philosophy will be better articulated.

Mr. Buncher, 43, hopes to reduce turnover and improve job satisfaction by giving regional division managers greater decision making powers. One reason for the large recent turnover, Mr. Buncher believes, is that regional managers had been reduced to carrying information to and from corporate management. "There were too many committees too far removed from problems that were making decisions by majority rule," Mr. Buncher said.

George P. Van (above) resigned after repeated clashes between his management style and that of Jack R. Anderson

Relations should be smoother between James E. Buncher (above) and Mr. Anderson who have closer management styles

Mr. Buncher worked for Abbott Labs and SCM Corp. prior to joining Affiliates. He says he will try to reconcile the conflicts between the freedom needed to maximize performance of entrepreneurial managers and needed management controls.

Some former executives cite top management's lack of decisiveness and the company's general lack of direction as their reasons for leaving. Said one,

Continued on page 18

Continued from page 15

prices down far enough.

Baxter stands to lose its busine with nine hospitals and three lon term care facilities if the JPC contra goes through. (Most of the other faci ties currently use Abbott product And the vendor will have to wait a lo time for a chance to get that busine back. The contract is for four-and- half years instead of the standard tw or three.

I.V. vendors are playing for kee these days because if committed vo ume contracts take hold there will big winners and big losers. Instead losing one hospital's business, a losi bidder may lose all its business in a area.

Vendors are testing hospital group said John Giampolo, director of th New Jersey Hospital Assn.'s purcha ing program. Abbott, Baxter an McGaw each have a group purchasi contracts manager whose job is t evaluate purchasing groups for mem ber loyalty, he affirmed. I.V. manufa turers bid accordingly.

Baxter didn't bid aggressively on committed volume I.V. contract NJH awarded to Abbott two years ago. Bu because 43 hospitals stuck with th group, Baxter took them seriously an came back to win a committed volum amino acids contract this year. The 5 hospitals that committed to the ne contract are getting discounts betwee 60% and 70% on the protein supplie ments.

If hospitals stick by their purchasing groups, they will achieve lower I.V. pricing for the long-term. But the temptation to take the best price no is strong. A hospital that has already saved $3,000 by working through a group has to weigh whether going outside the group and saving another $800 is worth higher prices in the lon run, Mr. Giampolo said.

After all, if a group hadn't brought prices down in the first place, other suppliers wouldn't make a lower offer, said Gene P. Abel, vice-chairman, Hos- pital Purchasing Service of Phila- delphia, PA. Prices can only go up again if hospitals renege on their commitment to a group.

The JPC contract is unusual in that individual hospitals can get an addi- tional discount below the group price on key items of their choice. These products could represent the majority of a hospital's volume, Mr. Novich said.

The contract prohibits price in- creases for the first 18 months and limits price hikes for the remainder of the contract. ■

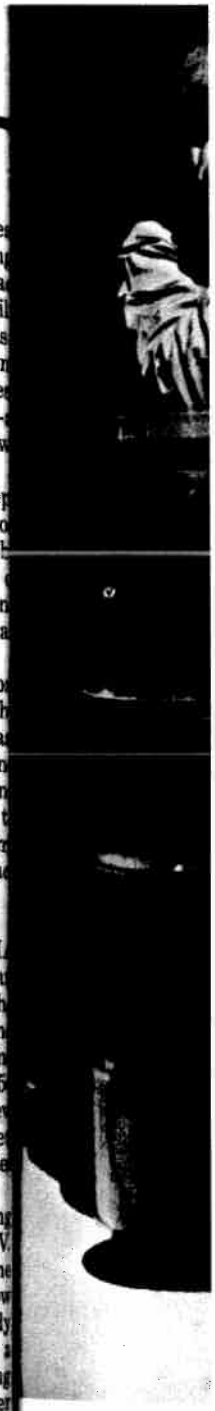

EXHIBIT BV

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY	MDL No. 1456
AVERAGE WHOLESALE PRICE	Master File No.
LITIGATION	01-CV-12257-PBS

THIS DOCUMENT RELATES TO:

United States of America, ex rel. Ven-A-Care of The Florida Keys, Inc., et al. vs. Boehringer Ingelheim Corporation, et al., Civil Action No. 07-10248-PBS

(Captions continued on following pages.)

VIDEOTAPED DEPOSITION OF PAUL CHESSER, a Witness, taken on behalf of the Defendants, before Robin Prouty, CCR No. 868, pursuant to Notice on the 24th day of June, 2008, at the offices of Kutak Rock, LLP, 124 West Capitol Avenue, Suite 2000, Little Rock, Arkansas.

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Q. Now, after this report in 1994, what was the next drug report that you became involved with?
A. It would be the -- the survey of AWP based on 1994 prices. The report -- we issued reports to 11 states and a couple roll-up reports.
Q. And that audit commenced around 1994; is that right?
A. It started -- in August of '94 was when the -- we officially kicked it off.
Q. And approximately how long did that audit last?
A. A long time.
Q. Can you define "a long time"?
A. Before all reports were issued, it was probably sometime in '96. I mean if you've got the dates on some of these. . . We had the work done -- the majority of the work done within a year.
Q. Okay. But the audit as a whole took a couple years, two to three years; is that right?
A. Yes.
Q. All right. Now, it appears that most of the audits you've worked on concern Medicaid drug

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prices --
A. Yes.
Q. -- is that correct. Did you ever have any involvement with Medicare reimbursement?
A. Not until recently with the passage of MMA and the Deficit Reduction Act. I've done some work. But we had an unwritten agreement, so to speak, Office of Audit did the Medicaid drug work, Office of -- OEI, Office of Evaluation and Inspections, did all the Medicare drug work.
Q. Okay. And both of those are underneath the Office of Inspector General, correct?
A. Correct.
Q. Okay. Are there any other offices other than OEI or OAS underneath the Office of Inspector General?
A. Office of Investigations.
Q. And what types of reports do they work on?
A. They don't do reports. They do criminal and civil investigations.
Q. So those are the three divisions of OIG, correct?

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A. Correct.
Q. And you've primarily worked with the Office of Audit Services?
A. Correct.
Q. And the office here in Little Rock, that's only the Office of Audit Services, correct?
A. Yes.
Q. Is there an Office of Evaluations and Inspections in Region 6?
A. Just a regional office.
Q. So that -- the OEI is entirely in the Dallas office; is that right?
A. For Region 6.
Q. For Region 6. Correct. Approximately how many audits have you been involved with with regard to Medicaid drug pricing?
A. I would have to add them up.
Q. Do you have a rough estimate? More than 20? More than 30?
A. Well, it would depend on -- I mean if you want to characterize that -- the '94 review as 11, 12, 13. We issued 13 reports. And to me, it was

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one -- one effort in terms of, you know, what you did. You did it in 11 different states. But if you count that as 13, it would be 30 or so, I would. . .
Q. Okay. So you would estimate you've worked on approximately 30 reports involved with audits of pharmaceutical drug pricing in the Medicaid program --
A. Yes.
Q. -- is that right. Okay. And you indicated that recently you started working with Medicare drug pricing; is that right?
A. Yes. The Medicare Modernization Act changed the way Medicare reimbursed for Part B drugs, physician-administered drugs, and that legislation actually included a provision that the OIG conduct a -- an audit of the physicians' ability -- in particular oncology physicians' ability to purchase cancer treatment drugs at that new reimbursement methodology of ASP plus six percent.
Q. And you indicated earlier there was an unwritten rule that OEI would do medicare drug

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other regions?
A. I never did personally. I think Bill Shrigley probably attended some -- some meetings where they might have talked about the various jobs going on, so he -- he would have done that for these jobs.
Q. You said George Reeb would have been the person to do that?
A. Bill Shrigley.
Q. Bill Shrigley. I'm sorry. Do you recall him ever discussing with you an occasion where he would have reported or shared results of an audit with other OIG officials from other regions?
A. I don't recall.
MR. HECK: I'm going to mark some exhibits. I think I'm going to mark four at this time.
(Whereupon, Exhibit Roxane 074 and Exhibit Roxane 075 were marked for identification by the reporter.)
MR. HECK: This is going to be Roxane 74. This is Roxane 75. 76. 77.

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(Whereupon, Exhibit Roxane 076 and Exhibit Roxane 077 were marked for identification by the reporter.)
Q. (By Mr. Heck) The court reporter is handing you what's been marked as four different exhibits, and I believe they run from 74 to 77. If you could take a moment to just flip through these. You don't have to read every word, just generally acknowledge what's there.
A. (Witness complies.)
Q. Okay?
A. Okay.
Q. All right. Now, drawing your attention to the top two exhibits, which I believe are 74 and 75. These are reports from the audits we were talking about earlier; is that correct?
A. Yes.
MR. DRAYCOTT: Objection.
Q. (By Mr. Heck) Just to be more specific, these are the reports that came out of the audits that began in 1994, and these were published in 1996 and '97; is that right?

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A. It looks like they both went out in '97.
Q. Okay. They were both in '97. And the first is the generic drug pricing report; is that right?
A. Yes.
Q. And the second is the brand name drug pricing report; is that right?
A. Yes.
Q. And these reports both came out of the same audit process; is that right?
A. Yes.
Q. And the goal of this process was to compare published AWPs, or average wholesale prices, to invoice prices; is that right?
A. Yeah. We state our objective as to develop an estimate of the difference between the actual invoice price and AWP.
Q. And what are you reading from right now?
A. That was out of the scope section.
Q. Of the branded drug report?
A. Yes.
Q. Or the generic report. Okay.

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A. They would have been worded identically.
Q. Now, these reports were both commissioned by HCFA; is that correct?
A. They were requested by HCFA.
Q. And let's move to Roxane Exhibit 76, which is a memorandum. Do you see that?
A. Yes.
Q. Do you recognize this document?
A. Yes.
MR. HECK: For those on the phone, this is a memorandum dated April 25th, 1994. It bears the Bates label HHD 21-0059 to 0061.
Q. (By Mr. Heck) Now, this appears to be a memorandum from someone at HCFA to John Hapchuk; is that correct?
A. Yes.
Q. Do you know who John Hapchuk is?
A. Yes, I do.
Q. And who is he?
A. At that time, John was a director at HCFA audit division working for George Reeb.
Q. Would he have been a colleague of Ben

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL INDUSTRY	:	MDL NO. 1456
AVERAGE WHOLESALE PRICE LITIGATION	:	CIVIL ACTION
THIS DOCUMENT RELATES TO:	:	01-CV-12257-PBS
United States of America ex rel.	:	
Ven-a-Care of the Florida Keys,	:	
Inc., v. Boehringer Ingelheim	:	
Corp., et al., Civil Action No.	:	
07-10248-PBS and United States of	:	
America, ex rel. Ven-A-Care of the	:	Hon. Patti B.
Florida Keys, Inc., v. Abbott	:	Saris
Laboratories, Inc., Civil Action	:	
Nos. 06-11337-PBS and	:	
07-CV-11618-PBS	:	

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(CROSS NOTICED CAPTIONS ON FOLLOWING PAGES)

Washington, D.C.

Tuesday, October 28, 2008

VOLUME II

PAUL CHESSER

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A. I don't know about that. What I -- what I recall about going painstakingly over every one of those rows of data, that the injectables seemed to have large discounts. And it was a challenge to know whether you were using the correct units.
Q. Could you explain that to me? How is -- how is that? What was the challenge there?
A. Well, I went back and reviewed everything where the discount was over a certain -- I don't remember what percent I used, or under a certain. And without a doubt, I had to go back and look at more NDCs that turned out to be injectables than anything else.
And part of the problem -- it was even a challenge to go back -- I used the Red Book as my reference. What they would show as the number of units for a particular NDC. That was the challenge, was getting -- making sure you were using the right units, because if I remember right at '94, we had a -- I don't think we had the package price. I think we had the unit price. I think we had to convert everything to unit price to be able to compare it to

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AWP.
So the challenge, when you got to the injectables, was there might be, say, a thousand milligrams but it's -- are there 10 of them in the package or not. And that was -- and ultimately, what proved to be the most reliable source for me was to go to the actual invoice, and see -- read the description of what the quantity was on that invoice. I couldn't necessarily rely on what the Red Book showed, or I think it was in 2000, '99 review, I was actually trying to use First DataBank's quantity for each NDC. But I spent more time on injectables than anything else in my review, investigating odd numbers.
Q. Because if it were a thousand milliliter bag, you could be off by a factor of a thousand if there were no --
A. 20 or -- I mean, the packaging of those is -- it's not the same from one reference source to another. And plus, I had to look up a lot of them because there were really significant discounts on some of them.

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BY MR. COOK:
Q. When you say significant discounts --
A. 90 plus percent.
Q. The analysis that you conducted of the invoices that were pulled in 1994, am I correct from my review of the spreadsheets that you had largely completed the analysis of those invoices and created the spreadsheets and done the basic calculations by April or May of -- of 1995? Or would you have to go back and look at the documents to see?
A. Yeah. I don't -- I don't remember.
Q. Okay. You had certainly collected all your data by that point, right?
A. I don't even know the answer to that for sure.
Q. But the documents would show presumably?
A. Yes.
Q. And just so we are clear, when you're referring to injectables, can you give me some examples of what types of drugs you're talking about with -- or products you're talking about with respect to injectables?

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A. Saline solution.
Q. So dextrose solution, for example, would be an injectable? Would you agree that sterile water would be an injectable?
A. Yes.
Q. If it were an IV bag, an IV solution antibiotic would be an injectable?
A. Yes.
Q. Do you know who Dr. Bruce Vladeck is?
A. He was the administrator at CMS for a little while.
Q. He was the administrator from 1992 to 1997. Does that sound right?
A. Close enough.
Q. Close enough. He testified earlier in this case, and testified that with respect to infusion products, injectable products, such as sodium saline solution, that his expectation was that he would see discounts of 99 percent obtainable through GPOs. Would that be consistent with the empirical data that you reviewed in 1994?
MR. DRAYCOTT: Objection.

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THE WITNESS: I don't -- I don't know that I looked at the data sufficiently to be able to draw that conclusion.
BY MR. COOK:
Q. Would it surprise you to see discounts in the 90 percent plus range for these injectables?
A. No. It was very common.
Q. Did you find that these products tended to be expensive products?
MR. DRAYCOTT: Objection.
THE WITNESS: No. I don't think they were.
BY MR. COOK:
Q. So a bag of saline, based upon your review of actual tens of thousands of pages of actual data, what would you expect to pay for a bag of saline solution?
A. Not much.
MS. ALBEE: Objection. Form.
BY MR. COOK:
Q. 70 cents, a dollar?
A. Oh, I don't -- it's been too long.

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Q. I'm told that we need to change the tape, so it's a good time for a break.
THE VIDEOGRAPHER: This concludes volume II, tape three, in the deposition of Paul Chesser. Off the record at 4:29.
(Recess.)
THE VIDEOGRAPHER: Here begins volume II, tape four, in the deposition of Paul Chesser. On the record at 4:34.
BY MR. COOK:
Q. Just in terms of timing, so I can place us in time, Mr. Chesser, the OAS investigation into the difference between average wholesale price and pharmacy acquisition cost was begun sometime prior to August of 1994, correct?
A. August of '94 is when we had the meeting with the state folks in Richmond, so sometime barely before that.
Q. All right. So I'm just trying to get sort of a starting point of when the investigation commenced. Is there a formal commencing of an investigation, a document or an event that you sort

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of look at as commencing an investigation?
MR. BEIMERS: Objection.
THE WITNESS: In this case, no. And at that time no. When we do -- we do audit start notices a lot currently. I don't know that we did them always at that time.
BY MR. COOK:
Q. Certainly by August 30th of 1994, in this case, you had commenced your audit, correct?
A. Correct.
Q. Is there a difference, and I don't know the answer, is there a difference between an audit and an investigation in OIG parlance?
A. Yes.
Q. What is the difference?
A. Well, we have in addition to the Office of Audit Services, we have an Office of Investigations. These are all special agents who are criminal investigators who work on criminal as well as civil cases. And a lot of times in conjunction with the Department of Justice.
Q. And what's an audit as opposed to an

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investigation?
A. An audit is just looking to see whether some criteria has -- is being complied with or not. Not necessarily whether it's legal or illegal. It's just whether it's economic -- economical and efficient way to provide services, or something along those lines.
Q. So you're still investigating it in the sense that you're looking at facts, but you're not necessarily investigating it because someone has made an accusation of improper conduct?
A. Correct. We are not looking for criminal or civil.
Q. Do you have any procedure that you -- that you use when you come across evidence of fraud or abuse in the course of an audit?
A. Yes. I personally haven't had to deal with that, but we are supposed to contact OI immediately because the rules of evidence are different when you're in a criminal environment than they are during an audit.
Q. In the course of your 1994 investigation,